Remarks:

In the Office Action dated March 23, 2007, claims 21-41, in the above-identified U.S. patent application were rejected. Reconsideration of the rejections is respectfully requested in view of the above amendments and the following remarks. Claims 21-35 and 37-41 remain in this application and claims 1-20 and 36 have been canceled.

Claims 21-41 were rejected under 35 USC §112, second paragraph as indefinite. Since Eudragit® RL and Eudragit® RS are the same as ammonio methacrylate copolymer Type A or Type B USP/NF, the trademarked terms "Eudragit® RL" and "Eudragit® RS" have been deleted from the claims. In view of these amendments applicants request that this rejection be withdrawn.

Claims 21-41 were rejected under 35 USC §103(a) as unpatentable over Canadian Pat. 2,149,052 in view of EP 0 421 921 A1 and Canadian Pat. 1,305,166. The objective of the present invention was to coat the tablets in a way that they would pass the esophagus without causing side effects yet the tablets would still rapidly dissolve in the patient's stomach. This was achieved by using either a coating containing a pore forming agent which dissolves in the stomach or a coating which dissolves rapidly in the stomach but not in the esophagus. As pointed out in applicant's prior response, the prior art does not suggest or disclose a coating that dissolves or is separated from the core during contact with digestive solution in the patient's stomach. The office action contends that the prior art uses cellulose acetate phthalate and thus would inherently have the same coating properties as in the recited claims. This is not

correct because cellulose acetate phthalate would not dissolve in the patient's stomach and thus a coating which uses cellulose acetate phthalate would require a pore forming agent in order for 30% of the administered amount of ibandronate to be released from the pharmaceutical formulation into the stomach as recited in the present claims. None of the prior art individually or in combination suggests a pore forming agent or suggests that 30% of the administered amount of ibandronate can be released from the pharmaceutical formulation into the stomach. The claims have been amended to clarify that when a coating is used which does not dissolve during contact with the digestive solution in a patient's stomach, a pore forming agent is used. Applicants contend that combining the cited prior art would result in a formulation which does not dissolve in the patient's stomach. Since none of the cited references disclose treating a bone disease with a formulation which has a core containing ibandronate and a coating which dissolves or separates from the core in the patient's stomach, applicants contend that the presently claimed invention would not be obvious in view of the prior art and request that this rejection be withdrawn.

Applicants respectfully submit that all of claims 21-35 and 37-41 are now in condition for allowance. If it is believed that the application is not in condition for allowance, it is respectfully requested that the undersigned attorney be contacted at the telephone number below.

In the event this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fee for such an extension together with any additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account No. 02-2135.

Respectfully submitted,

By 

Monica Chin Kitts
Attorney for Applicants
Registration No. 36,105
ROTHWELL, FIGG, ERNST & MANBECK, p.c.
Suite 800, 1425 K Street, N.W.
Washington, D.C. 20005
Telephone: (202)783-6040